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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/302,863 04/30/99 GOODWIN

R 2519

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HM22/0716

EXAMINER

ROMEO, D

ART UNIT	PAPER NUMBER
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1647

DATE MAILED:

07/16/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/302,863</b>	Applicant(s) <b>Goodwin et al.</b>	
	Examiner <b>David Romeo</b>	Art Unit <b>1647</b>	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on 19 Apr 2001

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 15-34 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 15-34 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19)  Notice of Informal Patent Application (PTO-152)

20)  Other: \_\_\_\_\_

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**DETAILED ACTION**

1. The amendment filed 04/19/2001 (Paper No. 14) has been entered. Claims 15-34 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. 5 Code not included in this action can be found in a prior Office action.

2. Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for "TACI"; while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, does not reasonably provide enablement 10 for "TACI-L".

Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or 4, does not reasonably provide enablement for a polypeptide encoded by a nucleic acid molecule 15 75% identical to SEQ ID NO: 1 or SEQ ID NO: 3 because % identity at the nucleotide level translates into a much lower % identity at the amino acid level and the instant specification the instant specification does not identify those amino acid residues in the amino acid sequence of a TACI or a TACI-L which are essential for their biological activity and structural integrity and those residues which are either expendable or substitutable.

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The rejection of record is applied to claims 29-34 for reasons of record because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4, does not reasonably provide enablement for "TACI" or "TACI-L".

It is acknowledged that the claims recite SEQ ID NO: 2 or SEQ ID NO: 4, or some variant thereof, but the claims fail to link SEQ ID NO: 2 or SEQ ID NO: 4, or some variant thereof, with "TACI" or "TACI-L".

5 Applicants argue that page 6, lines 4-13, and page 7, lines 10-19, define homologous analogs, and the final paragraph of page 5 and the first paragraph of page 7 give examples of essential amino acid residues. Applicants' arguments have been fully considered but they are not 10 persuasive. Page 6, lines 4-13, and page 7, lines 10-19 disclose "substantially homologous analogs and allelic variations". The final paragraph of page 5 and the first paragraph of page 7 teach "fragments". A teaching of "substantially homologous analogs and allelic variations" and "fragments" does not identify those amino acid residues in the amino acid sequence of a TACI or 15 a TACI-L which are essential for their biological activity and structural integrity and those residues which are either expendable or substitutable.

3. Claim(s) 15-28 are rejected under 35 U.S.C. § 112, second paragraph, because they recite the terms "TACI" and "TACI-L".

The rejection of record is applied to claims 29-34.

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Applicants argue that the specification has been amended to more clearly define the terms. Applicants' arguments have been fully considered but they are not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

5 4. Claims 15, 19, 20, 23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaudhary (6, cited by Applicants) in view of Bringman (a11).

The rejection of record is applied to claims 29-34.

Claims 15, 19, 20, 23, 25, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaudhary (6, cited by Applicants) in view of Bringman (a11) and further in 10 view of Bram (13, cited by Applicants).

Applicants argue that TACI could not be interpreted to include BJAB cells. Applicants' arguments have been fully considered but they are not persuasive. There is nothing in the instant specification that would distinguish the claimed method from the method taught by the cited references.

15 It is further noted that Bram (13, cited by Applicants) teaches the amino acid sequence of a human transmembrane lymphocyte receptor (TACI) (Figure 2) that is normally present in all B-cells (paragraph bridging pages 3-4). The amino acid sequence of TACI is 100% identical to Applicants' SEQ ID NO: 2. It is further noted that BJAB is a human B cell line. BJAB cells

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comprise a polypeptide that comprises an amino acid sequence selected from the group consisting of the amino acid sequence of SEQ ID NO: 2, the amino acid sequence of a fragment of SEQ ID NO: 2 wherein said fragment binds TACI-L, the amino acid sequence of a polypeptide encoded by a nucleic acid molecule that is at least 75% identical to SEQ ID NO: 1, and the amino acid sequence of amino acids 1-166 of SEQ ID NO: 2, absent evidence to the contrary.

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It is further noted that there are no structural limitations to the "fragments". A single amino acid is a "fragment". Receptor-ligand interactions involve the binding of the ligand to the receptor via contact of amino acids in the ligand with amino acids in the receptor.

New formal matters, objections, and/or rejections:

10

*Specification*

5. The amendment filed 03/19/2001 (Paper No. 14) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The paragraph at page 5, line 28; the paragraph 15 at page 5, line 31; the paragraph at page 6, line 27. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. See MPEP 608.01(p). The application as filed does not direct particular attention to

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specific portions of the referenced document where the subject matter being incorporated may be found.

Applicant is required to cancel the new matter in the reply to this Office action.

***Claim Rejections - 35 USC § 112***

5 6. The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 29, 30 are indefinite over the recitation of "protein comprises ... fragments" because it is unclear if the protein comprises continuous or discontinuous "fragments". The metes and bounds of the claim(s) are not clearly set forth. It is suggested that the claims recite "a fragment".

10 Claims 33, 34 recite the limitation "the fragment of the polypeptide". There is insufficient antecedent basis for this limitation in the claim. There is sufficient antecedent basis for the limitation "the fragments of the polypeptide".

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***Conclusion***

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, 10 however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN 15 NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING

20 SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

*David Romeo*  
DAVID ROMEO  
PRIMARY EXAMINER  
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JULY 14, 2001